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| 10/537,038 | 11/21/2005 | Michael Ausborn | DV/4-32794A | 1309 |
| 1095 7550 07/08/2009 | | | | |
| NOVARTIS | | | | |
| CORPORATE INTELLECTUAL PROPERTY | | | | |
| ONE HEALTH PLAZA 104/3 | | | | |
| EAST HANOVER, NJ 07936-1080 | | | | |
| EXAMINER | | | | |
| YOUNG, MICAH PAUL | | | | |
| ART UNIT | | PAPER NUMBER | | |
| 1618 | | | | |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/537,038

Applicant(s)

AUSBORN ET AL.

Examiner

MICAH-PAUL YOUNG

Art Unit

1618

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 April 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-16 is/are pending in the application.
- 4a) Of the above claim(s) 10-16 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-9 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SE-US)
Paper No(s)/Mail Date 6/1/05, 8/14/08
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Information Disclosure Statement

The information disclosure statements (IDS) submitted on 8/14/08 and 6/1/05 were filed properly. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Election/Restrictions

Applicant's election of Group I, claims 1-9 in the reply filed on 4/27/09 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-7 and 9 rejected under 35 U.S.C. 102(b) as being anticipated by Iwamoto et al (EP 0 761 211 hereafter '211). The claims are drawn to a microparticle comprising an active agent embedded in a biocompatible matrix and an ionic liquid.

The '211 patent teaches a microparticle comprising biocompatible polymers, ionic liquids and active agents (abstract). The biocompatible polymer is polyglycolic

acid (abstract, col. 1, lin. 1-19). The ionic liquids include ammonium salts of ionic quaternary surfactants, including tetradecyldimethylbenzylammonium chloride (TDBAC) and cetylpyridinium chloride (CPC) (col. 2, lin. 29-40). The active agents include analgesics such as naproxen (examples 1 and 2). The particles are extruded and cut into microparticles (examples). These disclosures render the claims anticipated.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combined disclosures of Iwamoto et al (EP 0 761 211 hereafter '211) in view of Bodmer et al (USPN 5,639,480 hereafter '480). The claims are drawn to a microparticle comprising an active agent embedded in a biocompatible matrix and an ionic liquid.

As discussed above the '211 patent discloses a microparticle formulation comprising a biocompatible polymer matrix, an active agent and an ionic surfactant.

The reference is silent to the specific active agents of the instant claims, although analgesics are listed. The reference indicates that a wide variety of active agents are usable in the formulation. The inclusion of the specific active agents of the instant claims into the microparticle formulation of the '211 would be obvious and well within the level of skill in the art. This can be seen in the '480 patent.

The '480 patent discloses a microparticle formulation comprising a biocompatible polymer such as polyglycolic lactic acid, an ionic surfactant and various active agents (col. 10, lin. 8-30). The active agents include peptides such as somatotropin or somastostatin (examples). It would have been obvious to include these peptides into the microparticle formulation of the '211 since they comprise identical carrier formulations.

With these aspects in mind it would have been obvious to combine the peptide compounds of the '480 patent into the carrier microparticle formulation of the '211 patent in order to provide a stable formulation useful in treating a variety of cancers. One of ordinary skill in the art would have been motivated to combine the prior art with an expected result of a stable cancer treatment.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MICAH-PAUL YOUNG whose telephone number is (571)272-0608. The examiner can normally be reached on Monday-Friday 7:00-4:30; every other Monday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael G. Hartley/
Supervisory Patent Examiner, Art Unit 1618

/MICAH-PAUL YOUNG/
Examiner, Art Unit 1618